



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0672]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reprocessed, single-use device labeling.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prominent and Conspicuous Mark of Manufacturers On Single-Use Devices--(OMB Control
Number 0910-0577)--Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (Pub. L. 109-43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket

submission database, FDA estimates that there are 67 establishments that distribute approximately 427 reprocessed SUDs. Each response is anticipated to take 0.1 hours (6 minutes) resulting in a total burden to industry of 43 hours.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden^{1,2}

Type of Respondent	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Establishments listing less than 10 SUDs	58	2	116	0.1 (6 minutes)	12
Establishments listing 10 or more SUDs	9	34	306	0.1 (6 minutes)	31
Total					43

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.